UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC., PRODUCTS LIABILITY LITIGATION	)	
	)	MDL No.: 2419
	)	Master Docket No.: 1:13-md-2419
THIS DOCUMENT RELATES TO:	)	
All Suits Naming St. Thomas Outpatient Neurosurgical Center.	)	

PLAINTIFFS' STEERING COMMITTEE'S REPLY IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT [Doc. 2300] AND OPPOSITION TO SAINT THOMAS CLINIC DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT [Doc. 2462]

The Plaintiffs' Steering Committee hereby files a Reply in Support of its Motion for Partial Summary Judgment (Doc. 2300) and Opposition to the Saint Thomas Clinic Defendants' Motion for Partial Summary Judgment (Doc. 2462). The PSC files this memorandum in order to address arguments made in the Saint Thomas Clinic Defendants' Memorandum in Support of their Motion for Partial Summary Judgment and Opposition to the PSC's Motion for Partial Summary Judgment (Doc. 2463).

INTRODUCTION

In violation of basic principles of statutory construction, the Tennessee Clinic Defendants encourage this Court to read the Tennessee Products Liability Act ("TPLA") in conflict with the Tennessee Health Care Liability Act ("THCLA"), to ignore the express terms of Tennessee's product liability statute, and to conclude that the Tennessee Legislature impliedly abrogated its long-standing statutory scheme for allocating loss caused by harmful and defective products. Based largely on out-of-state authority concerning other statutes in non-analogous contexts (such as how Massachusetts construes Article II of the Uniform Commercial Code), the Tennessee

Clinic Defendants posit that Tennessee has adopted a "predominance" test in determining whether the TPLA applies to claims involving medical providers. Tennessee has done no such thing, and the interaction between the THCLA and Tennessee's product liability statute compels the opposite conclusion. In essence, most of the facts and arguments referenced by the Tennessee Clinic Defendants are immaterial to whether injured tort victims are entitled to pursue statutory remedies premised upon harm caused by defective products. For the reasons discussed below, the Court should deny the cross-Motion for Partial Summary Judgment and grant the PSC's Motion for Partial Summary Judgment.

FACTUAL BACKGROUND

The PSC has already addressed certain facts and arguments in support of the PSC's Motion for Summary Judgment against St. Thomas Neurosurgical, which the PSC incorporates by reference.[1] Although the majority of the facts relied upon by the Tennessee Clinic Defendants are immaterial, the PSC has filed a Response to the Tennessee Clinic Defendants' Statement of Undisputed Material Facts along with this brief.

ARGUMENT

I. Tennessee's Principles of Statutory Construction

In an effort to distract this Court from the plain language of the TPLA, the Tennessee Clinic Defendants focus chiefly on matters external to the statute's express terms (treatises, other states' laws, etc.). The Tennessee Clinic Defendants ask this Court to ignore Tennessee's product liability statute without meaningfully applying basic principles of statutory construction to both the TPLA and THCLA.

[1] MDL D.E. 2302.

In construing a statute, the Court must ascertain and give effect to the legislative intent without unduly restricting or expanding a statute's coverage beyond its intended scope.[2] "It is the duty of a court 'to construe a statute so that no part will be inoperative, superfluous, void or insignificant, and the one section will not destroy another; and further to give effect to every word, phrase and sentence of the act in order to carry out the legislative intent."[3] Furthermore, in discerning legislative intent, courts employ the principle of *expressio unius est exclusio alterius,* which provides that "where the legislature includes particular language in one section of a statute but omits it in another section of the same act, it is generally presumed that the legislature acted purposefully in the subject included or excluded."[4]

When a court is asked to construe the interaction between two statutes, several principles apply. First, a construction that places "one statute in conflict with another **must be avoided**; therefore, [a court] **must resolve any possible conflict between statutes in favor of each other,** so as to provide **a harmonious operation of the laws**."[5] Indeed, the Tennessee Legislature actually codified that central premise of statutory construction by providing as follows in the Tennessee Code: "[i]f provisions of different titles or chapters of the code appear to contravene each other, **the provisions of each title or chapter shall prevail as to all matters and**

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[2] *Lee Med., Inc. v. Beecher*, 312 S.W.3d 515, 541 (Tenn. 2010) (citing *Owens v. State*, 908 S.W.2d 923, 926 (Tenn. 1995)).

[3] *Faust v. Metro. Gov't of Nashville & Davidson Cnty.*, 206 S.W.3d 475, 489 (Tenn. Ct. App. 2006) (quoting *Tidwell v. Collins*, 522 S.W.2d 674, 676-77 (Tenn. 1975)).

[4] *In re Kaliyah S.*, 455 S.W.3d 533, 554 (Tenn. 2015) (quotation omitted).

[5] *Graham v. Caples*, 325 S.W.3d 578, 582 (Tenn. 2010) (internal brackets and quotation omitted) (emphasis added); *see also State ex rel. Metro. Gov't of Nashville v. Spicewood Creek Watershed Dist.*, 848 S.W.2d 60, 62 (Tenn. 1993) ("[C]ourts should avoid a construction which places one statute in conflict with another," and "potential conflicts between statutes should be resolved in favor of each statute, if possible, to provide a harmonious operation of the laws") (citing *Parkridge Hosp., Inc. v. Woods*, 561 S.W.2d 754, 755 (Tenn. 1978)).

questions growing out of the subject matter of that title or chapter."[6] Second, "[w]here a conflict is presented between two statutes, a more specific statutory provision takes precedence over a more general provision."[7] Third, "the repeal of a statute by implication is not favored and there must be an irreconcilable conflict or repugnancy between the statutes that is plain and unavoidable to work a suspension of the earlier statute."[8]

II. Plaintiffs May Assert Claims Under Both The TPLA and the THCLA.

A. The TPLA: An All-Encompassing Scope for Products Liability Actions

The Tennessee Products Liability Act of 1978, codified at Tenn. Code Ann. § 29-28-101 *et seq.*, expressly authorizes claims for strict tort liability against sellers of defective or unreasonably dangerous products in certain limited circumstances, including when a product manufacturer is judicially declared insolvent.[9] The primary purpose of providing for seller liability "is to insure that where the manufacturer is insolvent, an injured party may look to a solvent seller for his losses."[10]

The statute sets forth the grounds for a strict liability cause of action against a "seller" or "distributor" of a product, and defines those terms broadly. A "'[s]eller includes a retailer, wholesaler, **or distributor**, and means **any individual or entity engaged in the business of selling a product**, whether such a sale is **for resale**, or **for use** or **consumption**."[11] This provision does not contain any qualifying language before the phrase "entity engaged in the

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[6] Tenn. Code Ann. § 1-3-103 (emphasis added).
[7] *Graham*, 325 S.W.3d at 582.
[8] *Oliver v. King*, 612 S.W.2d 152, 154 (Tenn. 1981); *see also Spence v. Miles Lab.*, 810 F. Supp. 952, 963-64 (E.D. Tenn. 1992) (finding no irreconcilable conflict between TPLA and a section of the Tennessee Code specific to the handling of AIDS-contaminated blood products, and construing statutes to be "harmonious").
[9] Tenn. Code Ann. § 29-28-106(5).
[10] *Seals v. Sears, Roebuck and Co., Inc.*, 688 F. Supp. 1252, 1256 (E. D. Tenn. 1988).
[11] Tenn. Code Ann. § 29-28-102(7) (emphases added).

business of selling of a product." A "product" means "any tangible object or goods produced."[12] There is no dispute that the MPA at issue was a "product" under the TPLA.

The TPLA also defines a "product liability action" broadly:

> "Product liability action" for purposes of this chapter **includes all actions** brought for or on account of personal injury, death or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product. "Product liability action" includes, **but is not limited to**, **all actions** based upon the following theories: strict liability in tort; negligence; breach of warranty, express or implied; breach of or failure to discharge a duty to warn or instruct, whether negligent, or innocent; misrepresentation, concealment, or nondisclosure, whether negligent, or innocent; or **under any other substantive theory in tort or contract whatsoever**.[13]

As the plain language indicates, the TPLA is written to give it maximal scope: it encompasses "all actions" involving personal injuries caused by "products" under "any substantive theory in tort or contract whatsoever."

The TPLA also contains certain limitations. Among other restrictions, it generally forbids a product liability action against "any seller, other than the manufacturer," unless (in relevant part) the manufacturer has been judicially declared insolvent.[14] In other words, the general rule is that only the manufacturer of a product can be held liable for harm caused by the product. However, when the manufacturer is insolvent (*i.e.*, is judgment-proof and cannot make the victim whole) or cannot be served with process, sellers are required to stand behind the product which they chose to sell, and they are required make innocent tort victims legally whole. The language of § 29-28-106(a)(3) does not contain any exceptions for particular industries.

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[12] Tenn. Code Ann. § 29-28-102(5).

[13] Tenn. Code Ann. § 29-28-102(6) (emphases added); *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 391 (6th Cir. 2013).

[14] Tenn. Code Ann. § 29-28-106(a)(3). The TPLA also exempts from its coverage breach of warranty actions otherwise covered by Tenn. Code Ann. § 47-2-101 *et seq.* (Tennessee's adoption of the Uniform Commercial Code Sales) and actions in which the manufacturer cannot be served with process and is otherwise not subject to service under the long-arm statute.

B. Unique Provisions Contained in the TPLA Reveal that Healthcare Providers Can be Product Sellers.

The Tennessee Products Liability Act contains a provision that is unique to Tennessee. That unique statutory provision reveals that healthcare providers can be considered sellers of harmful or defective products under Tennessee law.

The TPLA contains a statutory carve-out indicating that there is one circumstance and only one circumstance in which healthcare providers are not considered sellers of dangerous or defective products: when the product is a silicone breast implant.[15] In all other circumstances, Tennessee healthcare providers are subject to the same degree of seller liability as all other Tennessee businesses who sell harmful products.

Section 103(c) of the Tennessee Products Liability Act sets forth an extended statute of repose for actions against manufacturers or sellers of silicone breast implants.[16] The statute then carves out healthcare providers from the definition of the term "seller" for purposes of breast implant litigation ***only***. Specifically, Section 103(c) provides:

> (c)(1) Any action against a manufacturer or seller for injury to a person caused by a silicone gel breast implant must be brought within a period not to exceed twenty-five (25) years from the date such product was implanted; provided, that such action must be brought within four (4) years from the date the plaintiff knew or should have known of the injury.
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> (2) ***For purposes of this*** subsection ***(c) only***, "seller" does not include a hospital or other medical facility where the procedure took place, nor does "seller" include the physician or other medical personnel involved in the procedure.
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> (3) This subsection (c) only applies to causes of action not pending or decided on or before May 26, 1993. For the purposes of this subsection (c), a "pending case" is defined as a case actually filed by a silicone gel-filled breast implant recipient.[17]

[15] Tenn. Code Ann. § 29-28-103(c).
[16] Tenn. Code Ann. § 29-28-103(c)(1).
[17] Tenn. Code Ann. § 29-28-103(c)(emphasis added).

That specific and limited exclusion plainly and irrefutably demonstrates that the Tennessee legislature knew and intended that healthcare providers (*e.g.*, medical facilities and medical personnel) may be held liable as "sellers" in cases involving products *other than* silicone breast implants. Otherwise, the statutory carve-out would be completely superfluous and of no effect.

If the Legislature intended to immunize healthcare providers against product liability claims based on the sale of contaminated steroid injections, it would have singled out such claims for special treatment along with silicone breast implant cases. It did not do so. If the Legislature intended to immunize healthcare providers from seller liability generally, it could have stated such an exception in the statute. It did not.

The TPLA expressly excludes healthcare providers from seller liability in cases involving only one specific type of product (silicone breast implants), and no others. Under the rules of statutory construction, therefore, that one *specific* exclusion means that seller liability for healthcare providers is *not* excluded in cases involving any products *other than* silicone breast implants.[18]

The Tennessee Clinic Defendants cite no statute from any portion of the Tennessee Code stating that healthcare providers are not sellers of products. Instead, the Tennessee Clinic Defendants rely upon treatises and opinions from other jurisdictions, none of which discuss product liability statutes containing unique provisions like that of Tennessee.

[18] As discussed above, a well-established rule of statutory construction is "the maxim '*expressio unius est exclusio alterius*,' which states the principle that the expression of one thing implies the exclusion of all things not expressly mentioned." *Limbaugh v. Coffee Med. Ctr.*, 59 S.W.3d 73, 84 (Tenn. 2001). According to the Tennessee Supreme Court, "the mention of one subject in a statute means the exclusion of other subjects that are not mentioned. Omissions are significant when statutes are express in certain categories but not others." *Carver v. Citizen Utilities Co.*, 954 S.W.2d 34, 35 (Tenn. 1997) (citations omitted).

Moreover, the epidural steroid injections at issue are akin to those involved in a breast implantation: when a medical provider charges a fixed fee for a breast implantation (including the service and the cost of the implant), the cost of the implant constitutes only a small percentage of the total cost. Under the doctrine of *expressio unius*, the fact that the legislature identified that particular procedure for an exemption to the term "seller" indicates that it otherwise intended for the TPLA to cover injuries caused by defects in other products used in medical procedures, even when the product price reflects only a fraction of the overall charge for the procedure.

If this Court were to construe the statute as **never** applying to medical providers who perform medical procedures because those entities are not "sellers" under the TPLA, then § 103(c) and its subparts would be superfluous. Tennessee rules of statutory construction specifically require this Court **not** to interpret the statute in a manner that renders certain terms meaningless, that obliterates its plain meaning, and that contravenes the Legislature's intent as expressed in the words of the statute.

Taking § 103 and § 106 together and giving all of their provisions meaning, the plain language of the TPLA indicates that: (1) medical providers and medical facilities may constitute "sellers" of medical products inserted into patients (otherwise there would be no need for a special statutory carve-out relating to the implantation of silicone gel breast implants); and (2) with regard to the sale of products to patients, healthcare providers are subject to products liability if (and only if) the manufacturer is insolvent (or unable to be served with process) and cannot make the injured party whole.

The PSC has already explained why it is not "absurd" for Tennessee to have adopted this regime, and the PSC incorporates those arguments by reference.[19] As the PSC has explained, the Tennessee system is unique but not illogical: manufacturers are liable for injuries caused by their products in the first instance; but if the manufacturer is judgment proof or cannot be served, then the next entity in the chain is liable to the victim, regardless of the industry and the nature of the product at issue.

C. The THCLA's Narrow Focus On Healthcare Services

The Court has already considered and rejected the Tennessee Clinic Defendants' arguments concerning the THCLA in its August 29, 2014 Memorandum concerning multiple motions to dismiss filed by the defendants. The PSC will therefore limit its discussion here only to the most salient points.

Briefly, the THCLA defines a "health care liability action" as "any civil action . . . alleging that a health care provider or providers have caused an injury **related to the provision of**, or failure to provide, **health care services to a person**, regardless of the theory of liability on which the action is based."[20] The statute states that "health care services to persons" includes "care by health care providers which includes care by physicians, nurses, licensed practical nurses, pharmacists, . . . and other agents, employees, and representatives of the provider . . ."[21] The Act states that "any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint[.]" Among other things, the THCLA provides that a health care liability action can be proven by showing that (1) the defendant owed a duty of reasonable care to the claimant and breached that duty; and (2) the

[19] MDL D.E. 2302.
[20] Tenn. Code Ann. § 29-26-101(a)(1) (emphases added).
[21] Tenn. Code Ann. § 29-26-101(b).

breach of that duty is the legal cause of the claimant's injury.[22] The THCLA does not state, and no court has ever stated, that strict liability claims relating to medical **products** (as distinct from medical **services**) are precluded.

D. Interaction Between the THCLA and the TPLA Reveals That Plaintiffs May Assert Claims Under the TPLA Without Undermining the THCLA

Without any substantive discussion of the TPLA's terms, the defendants contend that the THCLA and the TPLA conflict and that the THCLA should control because it was passed (and amended) after the TPLA was enacted.[23] The defendants' facile approach ignores basic principles that courts must construe Tennessee statutes harmoniously and that a Court should be loath to find that the Legislature's clear intent in one statute was implicitly abrogated by another statute.[24] In addition, the defendants ignore the Tennessee Legislature's directive regarding statutory construction: "the provisions of each title or chapter shall prevail as to all matters and questions growing out of the subject matter of that title or chapter." [25] In short, the defendants gloss over the most important step in the Court's statutory analysis: can the language of the THCLA and the TPLA be reconciled?

The answer is to that question is yes. Both the THCLA and TPLA are all-encompassing within their spheres: the THCLA exclusively governs claims against a medical provider as they

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[22] Tenn. Code Ann. § 29-26-102(b)(2).
[23] Dkt. No. 2463 at 21-22.
[24] *Graham*, 325 S.W.3d at 582; *see also Spicewood*, 848 S.W.2d at 62 ("[C]ourts should avoid a construction which places one statute in conflict with another," and "potential conflicts between statutes should be resolved in favor of each statute, if possible, to provide a harmonious operation of the laws") (citing *Parkridge*, 561 S.W.2d at 755); *Oliver*, 612 S.W.2d at 154 ("The repeal of a statute by implication is not favored and there must be an irreconcilable conflict or repugnancy between the statutes that is plain and unavoidable to work a suspension of the earlier statute."); *see also Spence*, 810 F. Supp. at 963-64 (finding no irreconcilable conflict between TPLA and a section of the Tennessee Code specific to the handling of AIDS-contaminated blood products, and construing statutes to be "harmonious").
[25] Tenn. Code Ann. § 1-3-103.

relate to medical services themselves, while the TPLA exclusively governs claims against product sellers for harm caused by defective products if and when the product maker is insolvent. In other words, the THCLA governs claims arising from services provided by healthcare providers, while the TPLA governs claims that have nothing to do with the healthcare providers' conduct or services, *i.e.*, claims for harm caused by products. That construction of the two statutes gives meaningful effect to both. The Court's obligation is **not** to construe the two statutes as conflicting, if at all possible. The Court should therefore read the statutes harmoniously, not as in conflict.

The recent decision by the Tennessee Supreme Court in *Ellithorpe v. Weismark*, which found that certain amendments to the THCLA following the Tennessee Supreme Court's decision in *Estate of French v. Stratford House* abrogated *Estate of French*, is entirely consistent with the PSC's reasonable construction of the two statutes. In *Estate of French*, the Tennessee Supreme Court articulated a "nuanced approach" to determining whether certain forms of medical care were "basic", "administrative," or "routine," as opposed to "medical or professional" services covered by the THCLA.[26] In 2011, the Tennessee legislature amended the THCLA in a manner that abrogated that distinction (*i.e.*, its current form, in relevant part). In *Ellithorpe*, the Tennessee Supreme Court acknowledged that the legislature had effectively abrogated the distinction articulated in *Estate of French*, and therefore held the parents' claim that a clinical social worker "*was **negligent** in providing health services*" (emphasis in original) constituted the provision of health care services under the THCLA, thereby precluding causes of action for negligence and the intentional infliction of emotional distress.[27]

[26] *Estate of French v. Stratford House*, 333 S.W.3d 546, 559-60, 560 n.14 (Tenn. 2011).
[27] *Ellithorpe v. Weismark*, No. M2014-00279-SC-R11-CV, -- S.W.3d --, 2015 Tenn. LEXIS 827, at 19-24 (Tenn. Oct. 8, 2015).

Ellithorpe addresses only the viability of the particular distinction between "ministerial" services and "medical" services articulated in *Estate of French*, not whether the THCLA precludes product liability actions that involve the **sale of products** by a medical provider as opposed to whether the provider **breached a duty of care in the provision of medical services**. *Ellithorpe* at most reinforces the PSC's construction of the THCLA as all-encompassing only within its sphere. The THCLA governs claims arising from the decision making and conduct of healthcare providers when they provide medical services. It does not govern claims based exclusively on harm caused by defective products.

The Defendants also claim that the Tennessee Court of Appeals decision in *Burris v. Hospital Corp. of America*, 773 S.W.2d 932 (Tenn. App. 1989) supports their position.[28] It does not. *Burris* involved claims against a doctor for intentionally leaving a surgical medical device in a patient after a surgery and claims that his decision to do so violated the standard of care.[29] Nowhere in the decision does it appear that the plaintiff asserted a claim that the medical device at issue was unreasonably dangerous or that the device itself caused the injury.[30] Rather the inquiry appeared to be whether the doctor prudently chose to leave the medical device in the patient.[31] Unlike in *Burris*, plaintiffs' claims here under the TPLA involve strictly allegations that MPA injected into plaintiffs was unreasonably dangerous/defective and caused plaintiffs' personal injuries.[32] Those claims do not involve whatsoever the medical judgment of the

[28] Dkt. No. 2463 at 23.
[29] *Id*. at 933-34.
[30] *Id*.
[31] *Id*.
[32] Second Amended Master Complaint, Dkt. No. 1719 at ¶ 313-318.

medical providers.[33] *Burris*, therefore, provides no guidance on the issue of whether a healthcare provider can be liable as a "seller" for damage caused by an unreasonably dangerous product.

Accordingly, and contrary to the representations from the Saint Thomas Clinic Defendants, there is no reason for the Court to find that the THCLA implicitly abrogated the TPLA. No Tennessee case has addressed that issue (let alone reached that holding), and the Court should not (as the defendants would have it do) blithely find that there is a conflict between the subject statutes and that the Legislature's clear intention in one statute is no longer the law.

III. The Predominance Test is Irrelevant for Multiple Reasons

The defendants argue that they are absolved from liability under the TPLA because they "predominantly" engage in the business of providing medical services, not the sale of medical products. Their argument draws no support from the language of the TPLA, it relies on inapposite (and largely out-of-state) case law concerning application of the Uniform Commercial Code, and it is premised on misleading representations.

A. The TPLA Contains No Language Relating to a "Predominance Test" and Tennessee Courts Do Not Utilize that Test in Evaluating the TPLA's Applicability.

The TPLA defines a "seller" as anyone who "engaged in the business of selling a product." It does not qualify that definition with the terms "exclusively engaged," "primarily engaged," or "predominantly engaged." Nor does it limit the definition of "seller" by reference to the value or quantity of the goods sold. Indeed, as discussed above, the TPLA contemplates that providers of medical procedures for which the product inserted into a patient is only a

[33] Put differently, plaintiffs' claims under the TPLA could be maintained regardless of whether the doctor here satisfied the standard of care because as a "seller" of an "unreasonably dangerous" product, the Saint Thomas Clinic became subject to the TPLA.

fraction of the overall cost are included in the definition of "seller," except as to silicone gel breast implantation. The defendants essentially urge the Court to add qualifying language and limitations to the scope of the TPLA. Such an approach would contravene basic precepts of statutory construction, such as the tenet that courts should construe a statute as written and not to add limitations that are not contained within the statute's terms.

Notwithstanding the lack of limiting language in the statute, and the import of the silicone gel breast implant exception, the defendants contend that the Court should apply the "predominant factor" test because Tennessee employs that distinction in order to determine whether a particular "hybrid" transaction involves a good or a service. The defendants' contention that such test applies in the present context is invented out of whole cloth. The defendants conveniently omit any discussion of the context of the opinions upon which they rely: *i.e.*, in Tennessee, as in other jurisdictions, the "predominance test" is utilized to determine whether **Article II of the UCC applies to a particular transaction**.[34] The defendants cite no cases in which a Tennessee court applied the "predominance" test in order to determine whether liability attaches under the TPLA, nor has the PSC located any such authority after an exhaustive search. Indeed, the Tennessee Supreme Court already found **that the UCC definition of "seller" does not define the scope of the TPLA**, and that transactions not otherwise subject to Article 2 of the UCC are subject to the TPLA.[35]

Although the defendants contend that an entity otherwise defined as "health care provider" under the THCLA cannot be held liable as a "seller" under the TPLA, that is not how

[34] *See, e.g., Hudson v. Town & Country True Value*, 666 S.W.2d 51, 54 (Tenn. 1984).
[35] *See Baker v. Promark Prods. W., Inc.*, 692 S.W.3d 844, 847 (Tenn. 1985) (stating that "the legislature in the [TPLA] intended to extend protection for products liability injuries beyond the technical buyer-seller relationship encompassed by a strict interpretation of the Uniform Commercial Code").

courts applying Tennessee law have approached the issue. In *Graves v. Qualitest Pharmaceuticals*, a plaintiff sued two pharmaceutical companies, a pharmacy, and two individual (non-diverse) pharmacists, alleging wrongful conception due to the defendants' failure to warn her that contraceptives which she purchased had been recalled.[36] The defendants removed the case, and the pharmaceutical company defendants opposed remand on the basis that the individual pharmacists were fraudulently joined.[37] The pharmaceutical companies argued that the individual pharmacists could not be subject to liability because (among other things) the TPLA applied and shielded the individual pharmacists from liability because none of the exceptions to the TPLA applied.[38] The district court agreed that the definition of a "product liability action" under the TPLA is broadly worded and that the individual pharmacists' "alleged failure to warn about the mislabeling of the oral contraceptives placed [the plaintiffs' claims] within the definition of a 'product liability action.'"[39] The Court nevertheless held that the plaintiffs could maintain a TPLA against the pharmacists because the defendants had not shown that (under the alleged facts) they had no reasonable opportunity to inspect the contraceptives. The case is significant because the THCLA defines a pharmacist as a "health care provider," yet the *Graves* court held that the TPLA applied to the causes of action alleged against the pharmacist.

The defendants also cite numerous Massachusetts cases in support of their contention that the predominance test governs the application of the TPLA. Those citations have no bearing whatsoever on the issue presented: as the defendants acknowledge in a footnote, **Massachusetts**

[36] *Graves v. Qualitest Pharms.,* No.1:12-cv-01185-JDB-egb, 2013 U.S. Dist. LEXIS 87292 (W.D. Tenn. June 21, 2013).
[37] *Id.* at 2.
[38] *Id.* at 4.
[39] *Id.* at 9-10.

does not even permit a strict product liability cause of action based on a defective product in the first place. Moreover, how Massachusetts handles an entirely different statutory regime tells this Court nothing about Tennessee law, and it certainly provides the Court no insight as to how the Court should construe the specific intent of the Tennessee Legislature as it relates to the THCLA and the TPLA.

In sum, the predominance test was not intended to, and never has been, interpreted to limit liability under the TPLA or to define the reach of the THCLA. In contravention of the plain language of the TPLA, the defendants attempt to create a new definition of "seller" that requires the predominance test because, as they admit, they took money in exchange for epidural steroids.[40] Because the defendants provided MPA to patients in return for money, they fall squarely within the definition of seller under the TPLA. The defendants' motion should be denied, and the PSJ's motion should be granted.

IV. The Plaintiffs' Product Claims Fall Under the TPLA, not the THCLA

Plaintiffs' TPLA claims constitute "product liability actions" under the TPLA because they arise from harm caused by a **product,** not the quality of **services** provided by any defendant. Plaintiffs' TPLA claims are not premised upon any contention that any doctor drove the epidural needle too deep, that the medical providers failed to diagnose a particular condition, or that the providers recommended an inappropriate course of treatment – all of which would involve claims related to health care **services**. Instead, plaintiffs allege that medical providers sold and distributed contaminated MPA utilized in epidural steroid injections and that, because the manufacturer of the MPA is insolvent, the TPLA imposes liability upon those medical providers for inherent defects in the product.

[40] *See* Ex. 1 to D.E. 2302, Schamberg Dep. at 55.

The risk of loss should not fall upon innocent patients who played absolutely no role in importing NECC's products into Tennessee. Plaintiffs' TPLA claims do not depend on a breach of a standard of care or the healthcare providers' conduct in providing medical services – the product was either defective or it was not. Accordingly, strict liability claims based upon the contaminated nature of the product are governed by the TPLA, not the THCLA.

Although the defendants offer a grab bag of arguments as to why they do not constitute "sellers," the fact is that they expressly admitted – as they must – that they charged for the MPA administered to patients.[41] They did not give those products away for free. They sold them.

The third-party payor contracts identified by defendants do not prove otherwise: the contracts confirm that defendants are being reimbursed for the drugs – *i.e.*, that there is a payment for those drugs, notwithstanding scattered contractual references to "services."[42] The defendants also contend that they are not "sellers" because the dollar value of the MPA was a small fraction of the overall facility fee charged to patients. The defendants cite no Tennessee case law demonstrating that the dollar value of a sale has anything to do with the application of the TPLA. Indeed, by the defendants' logic, the silicone gel breast implant exception to the definition of "seller" would be superfluous under a predominance test because (by their logic) the silicone implant constitutes only a fraction of the overall purchase price for a silicone breast implantation procedure. To the contrary, the statute imposes no monetary threshold on the TPLA's scope or a proportionality requirement, even where an item represented only a fraction

[41] MDL D.E. 2467, Statement of Undisputed Facts 12(e).

[42] It is also disingenuous to suggest, as this argument does, that any party can exempt itself from a product liability action simply by stating in contracts that it provides "services" and not "products." Plaintiffs rely on these contracts simply for the clear and uncontradicted evidence that the contracts themselves contemplate reimbursement for the product in question, exhibiting that the defendant is receiving payment for the products at issue (i.e. selling the products at issue).

of the purchase price.[43] Whether a hospital charges $6 for a vial of MPA as part of a $1,000 transaction or $25,000 for a vial of an HIV cocktail as part of a $26,000 transaction makes no difference.

Two other arguments offered by the defendants to show that they are not "sellers" under the TPLA reflect a distinct lack of candor to the Court. First, the defendants argue that they are not "sellers" under Tennessee law because they did not charge sales tax for the MPA. What the defendants fail to mention is that prescription drugs are **exempt from sales and use tax in Tennessee**.[44] Essentially, the defendants argue that their failure to pay a tax that they do not owe somehow supports their position. Second, the defendants argue that the CMS definition of an ambulatory surgical center ("ASC") as a facility utilized "exclusively for the purpose of providing surgical services to patients" (*see* C.F.R. § 416.2) indicates that the clinics only perform "services" for purposes of the THCLA. The defendants are mixing apples and oranges. The CMS definition simply distinguishes an ASC from another type of medical facility based on the time frame in which each facility sees patients: to qualify as an ASC, a facility must exclusively see patients for whom hospitalization for an admission lasts no more than 24 hours.[45] The definition does not address, nor is it meant to address, whether the ASC exclusively performs a "service" rather than acts as a "seller" with respect to a particular transaction or series of transactions. All it means is that ASCs exclusively see patients for less than 24 hours following an admission.

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[43] *See Bissinger v. New Country Buffet*, No. M2011-02183-COA-R9-CV, 2014 Tenn. App. LEXIS 331 (Tenn. Ct. App. June 6, 2014) (where plaintiff became sick from eating contaminated oysters at an "all-you-can eat" buffet that he purchased, the TPLA applied to the suppliers of the product and did not shield them from a products liability action).

[44] Tenn. Code Ann. § 67-6-320.

[45] 42 C.F.R. § 416.2 (definition of "Ambulatory surgical center").

V. Policy Considerations

The defendants contend that it would be bad policy to hold them liable for selling MPA to patients, and that a holding in favor of the plaintiffs would leave hospital and medical service providers liable for all medical products billed directly or indirectly to patients or third-party payors. As an initial matter, it is the province of the Tennessee Legislature – not the courts – to make policy judgments concerning the scope of the THCLA and the TPLA.[46] Thus, it is for the Tennessee Legislature to decide what types of entities should be held liable for injuries from defective products and under what circumstances. The defendants essentially invite the Court to abrogate the plain language of the TPLA in order to advance what the defendants believe would be the best policy outcome (or at least provide the widest scope of immunity to physicians).

Regardless, as the PSC explained in support of its Motion for Summary Judgment, there are logical reasons for holding medical providers strictly liable for product defects (for products they sell) when the manufacturer is judgment-proof. Moreover, the parade of horribles outlined by the defendants is wildly overstated: medical providers are generally **immune** to a products liability action, **except** (in relevant part) when the injured party cannot be made whole because the manufacturer is not subject to service in Tennessee or is insolvent and therefore cannot pay. The statutory scheme arguably provides beneficial incentives to Tennessee-based medical providers: they can limit their potential liability by purchasing drugs and other medical products from **appropriately capitalized** and **appropriately insured** companies. Indeed, clinics and

[46] *See Smith v. Gore*, 728 S.W.2d 738, 747 (Tenn. 1987) ("All questions of policy are for the determination of the legislature, and not for the courts . . . . Where the courts intrude into their decrees their opinions on questions of public policy, they in effect constitute the judicial tribunals as lawmaking bodies in usurpation of the powers of the legislature.") (quoting *Cavender v. Hewitt*, 239 S.W.767, 768 (1921)).

hospitals are generally in a better position to absorb the cost of purchasing a bad product from an undercapitalized pharmaceutical company (such as NECC) than are innocent victims.

In the present case, the Tennessee Clinic Defendants ignored those incentives at their own peril: they purchased MPA from a manufacturer that was not sufficiently capitalized or insured. In so doing, the defendants assumed the responsibility under the TPLA to make innocent victims of contaminated products whole if and when the manufacturer is declared insolvent.

CONCLUSION

The Court should read the TPLA and the THCLA in harmony, not in conflict, and give effect to all of the language in both statutes. The plain language of the TPLA authorizes plaintiffs' product liability claims. Neither the TPLA nor the THCLA implicate or require a "predominance" test, and there is no need for the Court to find that the THCLA implicitly abrogated the TPLA. Because the defendants constitute "sellers" under the TPLA, the Tennessee Clinic Defendants' motion should be denied, and the PSC's Motion for Partial Summary Judgment should be granted.

Date: December 15, 2015

Respectfully submitted:

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing *Plaintiffs' Steering Committee's Opposition to the STOPNC Defendants' Motion for Partial Summary Judgment and Reply in Support of the PSC's Motion for Partial Summary Judgment* to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: December 15, 2015

/s/ Benjamin A. Gastel
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